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5/16/2002

h. 510(k) Summary of Safety and Effectiveness

1. General Company Information

Name:	Medafor, Inc.
Address:	5201 East River Road Suite 312 Minneapolis, MN 55421
Telephone:	763/ 571-6300
FAX:	763/571-1035
Contact:	Philip B. Jarvi, Director of Regulatory Affairs
Date Prepared:	September 26, 2001

2. General Device Information

Product Name:	HemaDerm™ containing Hemadex™ Clotting Beads
Classification:	Liquid Bandage, Class I (General Controls), Product Code – KMF

3. Predicate Devices

Calgon Vestal Labs, Kaltostat Wound Dressing

Hemostace, Sorbastace

Kendall Hydrophylic Powder Wound Dressing

Marine Polymer Technology Healtec and Syvek Patch

Dermaphylyx Calcium Alginate Wound Dressing

Closure Medical, Liquiderm Liquid Bandage

Marine Polymer Technology RDH Bandage

Vascular Solutions, Duett Flowable Hemostat

Hospal Tipstop Compression Dressing

4. Description

Medafor, Inc.'s HemaDerm™ consists of dry, sterile, controlled porosity, spherical particles manufactured from purified plant based polysaccharide. The porosity is controlled such that the particles act as molecular sieves excluding large proteins and cells.

The bleeding cessation is accomplished by the rapid dehydration and subsequent hemoconcentration of blood in contact with the particles. The concentration of serum proteins and cells produces a viscous gel. Normal platelet activation and fibrin deposition within the congealed blood produces a clot that limits further bleeding.

5. Indications

HemaDerm™ is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), minor cuts and lacerations.

HemaDerm™ is intended for use under the care of a health care professional for the local management and control of bleeding from percutaneous needle access, vascular access sites and percutaneous catheters.

6. Substantial Equivalence

This section summarizes information about the product and outlines the tests and clinical information we believe will provide sufficient data to support our claims of efficacy and safety.

Medafor, Inc.'s Hemadex® clotting beads consists of dry, sterile, controlled porosity, spherical particles manufactured from purified plant based polysaccharide using an emulsion cross-liking process.

The particles are packaged in single use containers with a moisture-protective laminate outer wrap. The final package is terminally sterilized using gamma irradiation. Contract manufacturers will do both packaging and sterilization, following written contracts with Medafor.

HemaDerm™ will be available for prescription use in sizes from .5 to 10 grams using either a medical grade plastic applicator package or a "peel and pour" laminate pouch.

The hemostatic effect of the particles is produced by the rapid dehydration and subsequent hemoconcentration of blood in contact with the particles. The concentration of serum proteins and cells produces a viscous gel. Normal platelet activation and fibrin deposition within the congealed blood produces a tenacious clot that limits further bleeding.

Biological testing per ISO 10993-1 and FDA G95-1 demonstrates the biological compatibility of HemaDerm™.

Sterilization validation of the Cobalt- 60 gamma irradiation process per AAMI / ANSI / ISO 11137 and EN552 demonstrate a sterility assurance level (SAL) of 1 X 10-6.

Animal testing using various animal models shows the efficacy of HemaDerm™ in the control of bleeding.

A non-significant risk clinical investigation using human subjects in a side by side comparison of HemaDerm™ and a control of normal clotting demonstrated an accelerated rate of bleeding control in the presence of the particles.

The indications is for topical application as an aid in the control of bleeding. This product will be intended for prescription use and labels are worded accordingly.

Medafor, Inc. believes that as a result of the biocompatibility testing, the physical analysis, the animal studies and the human clinical that the HemaDerm™ containing Hemadex™ clotting beads is safe and effective for the control of bleeding wounds and will perform in a manner equivalent and similar to the predicates. The device has been shown to effectively control bleeding. It has been demonstrated to be biocompatible per an internationally recognized standard and it has demonstrated to be procedurally and physiologically appropriate in medical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Medafor, Inc.
Philip B. Jarvi
Director, Clinical and Regulatory Affairs
5201 East River Road, #312
Minneapolis, Minnesota 55421-1035

Re: K021678
Trade Name: HemaDerm™ Containing Hemadex™ Clotting Beads
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 20, 2002
Received: May 21, 2002

Dear Mr. Jarvi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021678

Applicant: Medafor, Inc.

510(k) Number (if known):

Device name: HemaDerm™

Intended Use/Indications for Use:

HemaDerm™ is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), minor cuts and lacerations.

HemaDerm™ is intended for use under the care of a health care professional for the local management and control of bleeding from percutaneous needle access, vascular access sites and percutaneous catheters.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021678

Prescription Use X OR Over-The-Counter

(Per 21 CFR 801.109) (Optional Format 1-1-96)